

THIS REPORT CONTAINS ASSESSMENTS OF COMMODITY AND TRADE ISSUES MADE BY
USDA STAFF AND NOT NECESSARILY STATEMENTS OF OFFICIAL U.S. GOVERNMENT
POLICY

Voluntary - Public

Date: 4/5/2019

GAIN Report Number: IN9030

India

Post: New Delhi

Revised List of Antibiotics and Veterinary Drugs

Report Categories:

Sanitary/Phytosanitary/Food Safety

Exporter Guide

FAIRS Subject Report

Livestock and Products

Poultry and Products

Approved By:

Tiffany Landry

Prepared By:

Radha Mani

Report Highlights:

The Government of India's (GOI) Food Safety and Standards Authority of India (FSSAI) published a revised list of antibiotics and veterinary drugs along with their tolerance limits specified under the Food Safety and Standards (Contaminants, Toxins and Residues) Second Amendment Regulations, 2018. Implementation for the amended regulations began April 1, 2019.

General Information:

DISCLAIMER: The information contained in this report was retrieved from the FSSAI's website <http://www.fssai.gov.in/>. The Office of Agricultural Affairs, USDA and/or the U.S. Government make no claim of accuracy or authenticity.

On March 29, 2019, FSSAI notified a revised list of tolerance limits for antibiotics/veterinary drugs. The revisions listed in Annexure-I of the notification is a sub-set of the list earlier provided in the Food Safety and Standards (Contaminants, Toxins and Residues) Second Amendment Regulations, 2018.

The current notification also notes that antibiotics and veterinary drugs not listed in Annexure-I, but covered in the amendment regulations of July 2018, require modifications for either deletions or changes in their tolerance limits or changes in antibiotic/veterinary drug commodity combination. FSSAI has therefore delayed their implementation date until further orders. The modifications, when completed, will be published as amendments to the Regulations, inviting stakeholders' comments.

The full text of the current notification with Annexure-I is copied below and is available on FSSAI's website www.fssai.gov.in.

F. No. 1-100/SP(PAR)- Notification/Enf/FSSAI/2014(part file)
Food Safety and Standards Authority of India
(A Statutory Authority established under the Food Safety & Standards Act, 2006)
(Regulation division)
FDA Bhawan, Kotla Road, New Delhi-110 002

Dated, the 29th March, 2019

Subject: Direction under Section 16 (5) of Food Safety and Standards Act, 2006 regarding compliance of Food Safety and Standards (Contaminants, toxins and Residues) Second Amendment Regulations, 2018 published in the Official Gazette of India on dated 20th July, 2018 vide Notification No. 1-100/SP(PAR)- Notification/Enf/FSSAI/2014.

Reference is drawn to Food Safety and Standards (Contaminants, toxins and Residues) Second Amendment Regulations, 2018 published in the Official Gazette of India dated 20th July, 2018 vide Notification No. 1-100/SP(PAR)-Notification/Enf/FSSAI/2014. Based on the representation received from various stakeholders highlighting some important technical issues, the time line for compliance of said Food Safety and Standards (Contaminants, toxins and Residues) Second Amendment Regulations, 2018 was further extended up to 1st April, 2019.

2. Meanwhile, inputs/ representations were received from the stakeholders in respect of the challenges in complying with Tolerance Limits of the antibiotics and veterinary drugs and the same were referred to the Scientific Panel on Antibiotic Residues. Based on the recommendation of the Panel and with the approval of the competent authority the following has been decided:

3. Clause (2) of sub-regulation 2.3.2 of said amendment regulation and tolerance limit of 43 antibiotics and veterinary drugs for the food mentioned in clause (4) of sub-regulation 2.3.2 of said amendment regulation listed in Annexure-1(for which panel has not recommended any change) shall be enforced from 1st April, 2019.

4. However, compliance for other antibiotics and veterinary drugs of clause (4) is extended till further order. Meanwhile, the Food Authority will continue working on the regulation in respect of the remaining antibiotic/ Veterinary drugs for their possible deletion or changes in Tolerance limits or changes in antibiotic/ Veterinary drug-commodity combination. However, such modifications, if any, on the regulation shall follow the due process of amendment including stakeholders consultation.

5. This issues with the approval of the Competent Authority in exercise of the power vested with Food Authority under Section 16(5) of Food Safety and Standards Act, 2006.



(Pawan Agarwal)
Chief Executive Officer, FSSAI

Annexure - I

"(4) The antibiotics and veterinary Drugs specified in column (2) shall not exceed the tolerance limit specified in column (4) for the article of food in column (3) of the Table below, namely: -

S. No.	Name of the antibiotics and veterinary drugs	Food	Tolerance limit (mg/Kg)
(1)	(2)	(3)	(4)
1.	Ampicillin	(I) All edible animal tissues (II) Fats derived from animal tissues (III) Milk	0.01
2.	Amprolium	(I) All edible animal tissues except fish (II) Fats derived from animal tissues	0.01
3	Apramycin	(I) All edible animal tissues except fish (II) Fats derived from animal tissues (III) Milk	0.01
4.	Albendzole	Species not specified	
		Muscle	0.1
		Liver	5.0
		Kidney	5.0
		Fat	0.1
		Milk	0.1
		Fish	0.1
5.	Cloxacillin	(I) All edible animal tissues (II) Fats derived from animal tissue	0.01
6.	Chlortetracycline/Oxy tetracycline/Tetracycline	Cattle	
		Muscle	0.2
		Liver	0.6
		Kidney	1.2
		Milk	0.1
		Muscle	0.2
		Giant prawn(<i>Paeneus monodon</i>)(muscle)	0.2
		Pig	
		Muscle	0.2

S. No.	Name of the antibiotics and veterinary drugs	Food	Tolerance limit (mg/Kg)
(1)	(2)	(3)	(4)
		Liver	0.6
		Kidney	1.2
		Poultry	
		Muscle	0.2
		Liver	0.6
		Kidney	1.2
		Eggs	0.4
		Sheep	
		Muscle	0.2
		Liver	0.6
		Kidney	1.2
		Milk	0.1
		Cattle	
		Muscle	1.0
7.	Ceftiofur	Liver	2.0
		Kidney	6.0
		Fat	2.0
		Milk	0.1 mg/l
		Pig	
		Muscle	1.0
		Liver	2.0
		Kidney	6.0
		Fat	2.0
8.	Cephapirine	(I) All edible animal tissues except in fish. (II) Fats derived from animal tissues	0.01
9.	Clopidol	(I) All edible animal tissues except in fish. (II) Fats derived from animal tissues	0.01
10.	Closantel	Cattle	
		Muscle	1.0
		Liver	1.0
		Kidney	3.0
		Fat	3.0
		Sheep	
		Muscle	1.5
		Liver	1.5
		Kidney	5.0
		Fat	2.0
11.	Cefphactril	(I) All edible animal tissues except fish. (II) Fats derived from animal tissues (III) Milk	0.01

9m

		Milk	0.015
		Pig	
		Muscle	0.005
		Liver	0.1
		Kidney	0.03
14.	Diminazene	Fat	0.15
		Cattle	
		Muscle	0.5
		Liver	12.0
		Kidney	6.0
15.	Erythromycin	Milk	0.15
		Chicken	
		Muscle	0.1
		Liver	0.1
		Kidney	0.1
		Fat	0.1
		Eggs	0.05
		Turkey	
		Muscle	0.1
		Liver	0.1
16.	Flumequine	Kidney	0.1
		Fat	0.1
		Cattle	
		Muscle	0.5
		Liver	0.5
		Kidney	3.0

S. No.	Name of the antibiotics and veterinary drugs	Food	Tolerance limit (mg/Kg)
(1)	(2)	(3)	(4)
		Fat	1.0
		Chicken	
		Muscle	0.5
		Liver	0.5
		Kidney	3.0
		Fat	1.0
		Pig	
		Muscle	0.5
		Liver	0.5
		Kidney	3.0
		Fat	1.0
		Sheep	
		Muscle	0.5
		Liver	0.5
		Kidney	3.0
		Fat	1.0
		Trout	
		Muscle	0.5
17.	Flunixin	(I) All edible animal tissues except fish (II) Fats derived from animal tissues (III) Milk	0.01
18.	Febantel/Fenbendazole/Oxyfendazole	Cattle	
		Muscle	0.1
		Liver	0.5
		Kidney	0.1
		Fat	0.1
		Milk	0.1
		Pig	
		Muscle	0.1
		Liver	0.5
		Kidney	0.1
		Fat	0.1
		Sheep	
		Muscle	0.1
		Liver	0.5
		Kidney	0.1
		Fat	0.1
		Milk	0.1
		Goat	
		Muscle	0.1
		Liver	0.5
		Kidney	0.1
		Fat	0.1

S. No.	Name of the antibiotics and veterinary drugs	Food	Tolerance limit (mg/Kg)
(1)	(2)	(3)	(4)
19.	Ivermectin	Cattle	
		Milk	0.01
		Liver	0.8
		Fat	0.4
		Muscle	0.03
		Kidney	0.1
		Pig	
		Liver	0.015
		Fat	0.02
		Sheep	
		Liver	0.015
		Fat	0.02
20.	Lincomycin	Cattle	
		Milk	0.15
		Chicken	
		Muscle	0.2
		Liver	0.5
		Kidney	0.5
		Fat	0.1
		Pig	
		Muscle	0.2
		Liver	0.5
		Kidney	1.5
		Fat	0.1
21.	Levamisole	Cattle	
		Muscle	0.01
		Liver	0.1
		Kidney	0.01
		Fat	0.01
		Pig	
		Muscle	0.01
		Liver	0.1
		Kidney	0.01
		Fat	0.01
		Sheep	
		Muscle	0.01
		Liver	0.1
		Kidney	0.01
		Fat	0.01
		Poultry	

S. No.	Name of the antibiotics and veterinary drugs	Food	Tolerance limit (mg/Kg)
(1)	(2)	(3)	(4)
		Muscle	0.01
		Liver	0.1
		Kidney	0.01
		Fat	0.01
22.	Monensin	Cattle	
		Muscle	0.01
		Liver	0.1
		Kidney	0.01
		Fat	0.1
		Milk	0.002
		Sheep	
		Muscle	0.01
		Liver	0.02
		Kidney	0.01
		Fat	0.1
		Goat	
		Muscle	0.01
		Liver	0.02
		Kidney	0.01
		Fat	0.1
		Chicken	
		Muscle	0.01
		Liver	0.01
		Kidney	0.01
		Fat	0.1
		Turkey	
		Muscle	0.01
		Liver	0.01
		Kidney	0.01
		Fat	0.1
		Quail	
		Liver	0.01
		Kidney	0.01
		Muscle	0.01
		Fat	0.1
23.	Moxidectin	Cattle	
		Muscle	0.02
		Liver	0.1
		Kidney	0.05
		Fat	0.5
		Sheep	
		Muscle	0.05
		Liver	0.1
		Kidney	0.05

S. No.	Name of the antibiotics and veterinary drugs	Food	Tolerance limit (mg/Kg)
(1)	(2)	(3)	(4)
		Fat	0.5
24.	Meloxicam	(I) All edible animal tissues except fish (II) Fats derived from animal tissues (III) Milk	0.01
25.	Neomycin	Cattle	
		Liver	0.5
		Milk	1.5
		Kidney	10
		Fat	0.5
		Muscle	0.5
		Chicken	
		Liver	0.5
		Eggs	0.5
		Muscle	0.5
		Kidney	10
		Fat	0.5
		Duck	
		Fat	0.5
		Liver	0.5
		Kidney	10
		Muscle	0.5
		Goat	
		Liver	0.5
		Kidney	10
		Fat	0.5
		Muscle	0.5
		Pig	
		Kidney	10
		Liver	0.5
		Muscle	0.5
		Fat	0.5
		Sheep	
		Kidney	10
		Muscle	0.5
		Fat	0.5
		Liver	0.5
		Turkey	
		Liver	0.5
		Muscle	0.5
		Kidney	10
		Fat	0.5
26.	Nicarbazin	Chicken	

S. No.	Name of the antibiotics and veterinary drugs	Food	Tolerance limit (mg/Kg)
(1)	(2)	(3)	(4)
		Kidney	0.2
		Fat/Skin	0.2
		Liver	0.2
		Muscle	0.2
27.	Oxybendazole	(I) All edible animal tissues except in Fish (II) Fats derived from animal tissues	0.01
28.	Oxyclozanide	(I) All edible animal tissues except Fish (II) Fats derived from animal tissues (III) Milk	0.01
29.	Parbendazole	(I) All edible animal tissues except Fish (II) Fats derived from animal tissues (III) Milk	0.01
30.	Praziquantel	(I) All edible animal tissues except Fish (II) Fats derived from animal tissues (III) Milk	0.01
31.	Spectinomycin	Cattle	
		Muscle	0.5
		Liver	2.0
		Kidney	5.0
		Fat	2.0
		Milk	0.2 mg/l
		Chicken	
		Muscle	0.5
		Liver	2.0
		Kidney	5.0
		Fat	2.0
		Eggs	2.0
		Pig	
		Muscle	0.5
		Liver	2.0
		Kidney	5.0
		Fat	2.0
		Sheep	
		Muscle	0.5
		Liver	2.0

S. No.	Name of the antibiotics and veterinary drugs	Food	Tolerance limit (mg/Kg)
(1)	(2)	(3)	(4)
		Kidney	5.0
		Fat	2.0
32.	Sulfadiazine	(I) All edible animal tissues (II) Fats derived from animal tissues (III) Milk	0.01
33.	Sulfanilamide	(I) All edible animal tissues (II) Fats derived from animal tissues (III) Milk	0.01
34.	Sulfaquinoxaline	(I) All edible animal tissues except fish (II) Fats derived from animal tissues (III) Milk	0.01
35.	Sulfadimidine	Cattle	
		Milk	0.025
		No Specified	
		Muscle	0.1
		Fat	0.1
		Kidney	0.1
		Liver	0.1
36.	Sulfa Chloropyrazine	(I) All edible animal tissues except fish (II) Fats derived from animal tissues (III) Milk	0.01
37.	Thiabendazole	Cattle	
		Muscle	0.1
		Liver	0.1
		Kidney	0.1
		Fat	0.1
		Milk	0.1
		Pig	
		Muscle	0.1
		Liver	0.1
		Kidney	0.1
		Fat	0.1
		Sheep	
		Muscle	0.1
		Liver	0.1
		Kidney	0.1
		Fat	0.1
		Goat	
		Muscle	0.1

S. No.	Name of the antibiotics and veterinary drugs	Food	Tolerance limit (mg/Kg)
(1)	(2)	(3)	(4)
		Liver	0.1
		Kidney	0.1
		Fat	0.1
		Milk	0.1
38.	Triclabendazole	Cattle	
		Muscle	0.25
		Liver	0.85
		Kidney	0.4
		Fat/Skin	0.1
		Sheep	
		Muscle	0.2
		Liver	0.3
		Kidney	0.2
		Fat/Skin	0.1
39.	Trimethoprim	(I) All edible animal tissues except fish (II) Fats derived from animal tissues (III) Milk	0.01
40.	Tylosin	Cattle	
		Muscle	0.1
		Liver	0.1
		Kidney	0.1
		Fat	0.1
		Milk	0.1
		Pig	
		Muscle	0.1
		Liver	0.1
		Kidney	0.1
		Fat	0.1
		Sheep	
		Muscle	0.1
		Liver	0.1
		Kidney	0.1
		Chicken	
		Muscle	0.1
		Liver	0.1
		Kidney	0.1
		Fat/Skin	0.1
		Eggs	0.3
41.	Virginiamycin	(I) All edible animal tissues except in Fish (II) Fats derived from animal tissues	0.01

S. No.	Name of the antibiotics and veterinary drugs	Food	Tolerance limit (mg/Kg)
(1)	(2)	(3)	(4)
		(III) Milk	
42.	Xylazine	(I) All edible animal tissues except fish (II) Fats derived from animal tissues	0.01
43.	Zinc Bacitracin (minimum 60IU/mg dried substance)	(I) All edible animal tissues except in Fish (II) Fats derived from animal tissues	0.01